

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/30/2009 has been entered.

Applicant's amendment, filed on 12/30/2009, has been entered.

Claims 161 and 162 have been amended.

Claims 1-144, 146, 148 and 154-160 have been canceled previously.

Claims 145, 147, 149-153 and 161-164 are pending.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Action will be in response to applicant's arguments, filed 04/16/2009.

### **3. Priority.**

Upon reconsideration of the recitation of applicant's amended and newly added claims, filed 04/16/2009, the effective filing date of the instant claims is deemed to be the filing date of the priority document USSN 09/249,011, filed 02/12/1999.

4. The substitute sequence submission in conjunction with the Mittler Hawkins-type Declaration from priority application USSN 09/249,011, has been entered and is in compliance with 37 CFR 1.125(b).

5. Upon reconsideration of applicant's amended claims, filed 01/25/2010, the previous rejections under 35 U.S.C. 112, second paragraph, have been withdrawn.

6. Upon reconsideration of applicant's amended claims, filed 01/25/2010 in conjunction with the Mittler Hawkins-type Declaration from priority application USSN 09/249,011 and the updated sequence submission and compliance;

the previous rejection under 35 U.S.C. § 112, first paragraph, enablement with respect to the III2R and H2F antibodies / immunoglobulins has been withdrawn

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7. Claims 145, 147, 149-153 and 161-164 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable  
over claims 1-61 of U.S. Patent No. 6,827,934 for the reasons of record,  
over claims 1-18 of U.S. Patent No. 6,984,383 (1449; #AA) for the reasons of record and \  
over claims 1-61 of U.S. Patent No. 7,531,175.

The patented claims drawn to methods of therapeutic regimens of transplantation with B7-specific antibodies either anticipate or render obvious the instant claims.

The claims of U.S. Patent No. 7,531,175 are similarly drawn to methods of inhibiting immune response in a transplantation regimen, including reliance upon the same or nearly the same 1F1 anti-B&-1 antibody as well as the same III2R framework regions as the instant claimed methods.

Also, as to the use of a combination of immunosuppressive therapy in transplantations therapeutic regimens or timing of administration of immunosuppressive agents during transplantation regimens,

methods of administration are a result effective variable and immunosuppressive therapy including rapamycin were routine at the time the invention was made by the ordinary artisan.

It is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). See also Merck & Co. v. Biocraft Labs. Inc., 874 F.2d 804, 809, 10 USPQ2d 1843, 1847-48 (Fed. Cir. 1989) (determination of suitable dosage amounts in diuretic compositions considered a matter of routine experimentation and therefore obvious).

Applicant's remarks respectfully request that the Examiner hold in abeyance all obviousness-type double patenting rejections until allowable subject matter is indicated is acknowledged.

The obviousness-type double patenting rejections are the only rejections remaining in this application and are maintained for the reasons of record.

8. Claims 145, 147, 149-153 and 161-164 are directed to an invention not patentably distinct f  
from claims 1-61 of commonly assigned U.S. Patent No. 6,827,934;  
from claims 1-18 of commonly assigned U.S. Patent No. 6,984,383 (1449; #AA) and  
from claims 1-61 of commonly assigned U.S. Patent No. 7,531,175  
for the reasons of record and above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No., discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting

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inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004

9. No claim allowed.

10. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/  
Primary Examiner  
Art Unit 1644  
Technology Center 1600  
March 28, 2010